

the product as an “alertness aid” or a “stimulant.”

(b) *Indications.* The labeling of the product states, under the heading “Indications,” the following: “Helps restore mental alertness or wakefulness when experiencing fatigue or drowsiness.” Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph (b), may also be used, as provided in § 330.1(c)(2), subject to the provisions of section 502 of the Act relating to misbranding and the prohibition in section 301(d) of the Act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the Act.

(c) *Warnings.* The labeling of the product contains the following warnings under the heading “Warnings”:

(1) “The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat.”

(2) “For occasional use only. Not intended for use as a substitute for sleep. If fatigue or drowsiness persists or continues to recur, consult a” (select one of the following: “physician” or “doctor”).

(3) “Do not give to children under 12 years of age.”

(d) *Directions.* The labeling of the product contains the following information under the heading “Directions”: Adults and children 12 years of age and over: Oral dosage is 100 to 200 milligrams not more often than every 3 to 4 hours.

PART 341—COLD, COUGH, ALLERGY, BRONCHODILATOR, AND ANTI-ASTHMATIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Sec.

341.1 Scope.

341.3 Definitions.

Subpart B—Active Ingredients

- 341.12 Antihistamine active ingredients.
- 341.14 Antitussive active ingredients.
- 341.16 Bronchodilator active ingredients.
- 341.18 Expectorant active ingredient.
- 341.20 Nasal decongestant active ingredients.

Subpart C—Labeling

- 341.70 Labeling of OTC drug products containing ingredients that are used for treating concurrent symptoms (in either a single-ingredient or combination drug product).
- 341.72 Labeling of antihistamine drug products.
- 341.74 Labeling of antitussive drug products.
- 341.76 Labeling of bronchodilator drug products.
- 341.78 Labeling of expectorant drug products.
- 341.80 Labeling of nasal decongestant drug products.
- 341.90 Professional labeling.

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

Subpart A—General Provisions

§ 341.1 Scope.

(a) An over-the-counter cold, cough, allergy, bronchodilator, or anti-asthmatic drug product in a form suitable for oral, inhalant, or topical administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this part and each of the general conditions established in § 330.1.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

[51 FR 35339, Oct. 2, 1986]

§ 341.3 Definitions.

As used in this part:

(a) *Bronchodilator drug.* A drug used to overcome spasms that cause narrowing of the bronchial air tubes, such as in the symptomatic treatment of the wheezing and shortness of breath of asthma.

(b) *Oral antitussive drug.* A drug that either is taken by mouth or is dissolved in the mouth in the form of a lozenge and acts systemically to relieve cough.

§ 341.12

(c) *Topical antitussive drug.* A drug that relieves cough when inhaled after being applied topically to the throat or chest in the form of an ointment or from a steam vaporizer, or when dissolved in the mouth in the form of a lozenge for a local effect.

(d) *Expectorant drug.* A drug taken orally to promote or facilitate the removal of secretions from the respiratory airways.

(e) *Antihistamine drug.* A drug used for the relief of the symptoms of hay fever and upper respiratory allergies (allergic rhinitis).

(f) *Oral nasal decongestant drug.* A drug that is taken by mouth and acts systemically to reduce nasal congestion caused by acute or chronic rhinitis.

(g) *Topical nasal decongestant drug.* A drug that when applied topically inside the nose, in the form of drops, jellies, or sprays, or when inhaled intranasally reduces nasal congestion caused by acute or chronic rhinitis.

(h) *Calibrated dropper.* A dropper calibrated such that the volume error incurred in measuring any liquid does not exceed 15 percent under normal use conditions.

[51 FR 35339, Oct. 2, 1986, as amended at 54 FR 8509, Feb. 28, 1989; 55 FR 40382, Oct. 3, 1990; 57 FR 58374, Dec. 9, 1992; 59 FR 43409, Aug. 23, 1994]

Subpart B—Active Ingredients

§ 341.12 Antihistamine active ingredients.

The active ingredient of the product consists of any of the following when used within the dosage limits established for each ingredient:

- (a) Brompheniramine maleate.
- (b) Chlorcyclizine hydrochloride.
- (c) Chlorpheniramine maleate.
- (d) Dexbrompheniramine maleate.
- (e) Dexchlorpheniramine maleate.
- (f) Diphenhydramine citrate.
- (g) Diphenhydramine hydrochloride.
- (h) Doxylamine succinate.
- (i) Phenindamine tartrate.
- (j) Pheniramine maleate.
- (k) Pyrilamine maleate.
- (l) Thonzylamine hydrochloride.
- (m) Triprolidine hydrochloride.

[57 FR 58374, Dec. 9, 1992, as amended at 59 FR 4218, Jan. 28, 1994]

21 CFR Ch. I (4–1–02 Edition)

§ 341.14 Antitussive active ingredients.

The active ingredients of the product consist of any of the following when used within the dosage limits and in the dosage forms established for each ingredient in § 341.74(d):

(a) *Oral antitussives.* (1) Chlophedianol hydrochloride.

(2) *Codeine ingredients.* The following ingredients may be used only in combination in accordance with §§ 329.20(a) and 341.40 and 21 CFR 1308.15(c).

- (i) Codeine.
- (ii) Codeine phosphate.
- (iii) Codeine sulfate.
- (3) Dextromethorphan.
- (4) Dextromethorphan hydrobromide.
- (5) Diphenhydramine citrate.
- (6) Diphenhydramine hydrochloride.
- (b) *Topical antitussives.*
 - (1) Camphor.
 - (2) Menthol.

[52 FR 30055, Aug. 12, 1987, as amended at 59 FR 29174, June 3, 1994]

EFFECTIVE DATE NOTE: At 67 FR 4907, Feb. 1, 2002, § 341.14 was amended in paragraph (a)(2) by removing “§§ 329.20(a) and 341.40” and by adding in its place “§ 290.2”, effective Apr. 2, 2002.

§ 341.16 Bronchodilator active ingredients.

The active ingredients of the product consist of any of the following when used within the dosage limits established for each ingredient:

- (a) Ephedrine.
- (b) Ephedrine hydrochloride.
- (c) Ephedrine sulfate.
- (d) Epinephrine.
- (e) Epinephrine bitartrate.
- (f) Racephedrine hydrochloride.
- (g) Racepinephrine hydrochloride.

[51 FR 35339, Oct. 2, 1986]

§ 341.18 Expectorant active ingredient.

The active ingredient of the product is guaifenesin when used within the dosage limits established in § 341.78(d).

[54 FR 8509, Feb. 28, 1989]

§ 341.20 Nasal decongestant active ingredients.

The active ingredient of the product consists of any of the following when used within the dosage limits and in the dosage forms established for each ingredient: